

## REMARKS

### Accompanying Declaration

A Declaration of Howard Maibach, M.D. under 37 C.F.R. §1.132 accompanies this Response.

### Presented Claims

Claims 1, 2, 4, 5, 7-11, 13, and 15-22 are pending and presented for consideration.

### Discussion of Rejections

There are two 35 U.S.C. §103 rejections made against the claims. These rejections are essentially identical to the rejections made previously in the September 10, 2002 Office action. Applicant believes she fully responded to those rejections in her March 10, 2003 Amendment Under 37 C.F.R. §1.111 -- pointing out in detail (1) why the references failed to teach all the limitation of the claims (2) why the references failed to provide motivation to combine their teachings and (3) why there was no reasonable expectation of success in combining the references.

Applicant requests the Examiner to reconsider the merits of Applicant's previous response in light of Dr. Maibach's declaration and the following comments.

In Applicant's previous response, it was pointed out that Fitzjarrell's topical sprays are particularly intended for administration to the face; whereas Applicant's fine mist spray of salicylic acid -- even with its reduced tendency to induce nasal irritation and coughing -- is not suitable for application as such to the face. The final rejection states that the claims recitation "for administration as such only for non-facial body skin" is merely directed to an intended use and not a structural limitation and that no patentable weight is given to the preamble. That statement ignores the fact that the preamble recites that it is a fine mist pump spray that is for administration as such only to non-facial body areas. That recitation is a structural limitation. Further, the body of the claims recites that the fine mist spray is one of salicylic acid -- another

structural limitation. Further, the record of this application is replete with evidence that fine mist sprays of salicylic acid are not suitable for facial administration.

As regards Fitzjarrell, Applicant directs the Examiner to paragraph 5 c) of Dr. Maibach's declaration. In that paragraph Dr. Maibach points out that Fitzjarrell "says nothing about fine mist sprays and only mentions salicylic acid as an anti-acne treatment in the context of creams" and "also says nothing about the irritation/coughing problem experienced by Ms. Baker or how that problem might be solved." He further points out that Fitzjarrell specifically recommends his formulations for use on the face and concludes "This is a further indication that Fitzjarrell's teachings are unrelated to fine mist sprays."

Applicant's previous response also stressed the point that none of the references recognizes the coughing /irritation problem associated with fine mist sprays of salicylic acid (because none involves fine mist sprays) or Applicant's solution of raising the pH of the composition to above about 5. The final rejection states "the recitation 'whereby the likelihood of the fine mist spray causing nasal irritation and coughing is reduced' is viewed as an obvious property of the solution having pH of above about 5..." Not only is that view not supported by any teaching in the references, but it is also rebutted by paragraphs 5 b) and d) of Dr. Maibach's declaration. Paragraph 5 b) indicates that neither the coughing/irritation problem nor Applicant's solution thereto was obvious to Dr. Maibach (a renowned expert in dermatology) and that Dr. Maibach believes the same would not be obvious to others. More to the point, paragraph 5 d), after noting that the secondary references do not anticipate that problem and solution states "...I disagree with the conclusion reached in the June 4, 2003 Office Action that the reduction in nasal irritation and coughing at pHs above 5 is an obvious property of the solution. It is only when the solution is administered as a fine mist spray that this problem exists and none of the three patent references referred to above describes fine mist sprays of salicylic acid."

Finally, Applicant's previous response maintained that there would be no likelihood of success of combining the references because of the coughing/irritation problem associated with fine mist sprays of salicylic acid. The final rejection states "It would have been obvious to one

ordinary skill in the art at the time the invention was made to have modified the spray composition of Fitzjarrell by substituting salicylic acid for the anti-acnes employed in the patent because of the expectation of successfully producing a mild anti-acne spray solution.” well, it was not obvious to a person of extremely high skill in the art, Dr. Maibach. Paragraph 5(e) of Dr. Maibach’s declaration states

“In view of the difficulties with nasal irritation and coughing associated with administering fine mist sprays of salicylic acid, I disagree with the June 4, 2003 Office Action’s contention that there was an expectation that one could successfully produce a spray, particularly a fine mist spray, of salicylic acid by replacing niacinamide with salicylic acid in the Fitzjarrell composition”.

## CONCLUSION

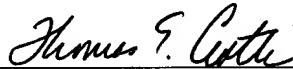
Applicant submits that for the reasons stated in her March 10, 2003 Amendment, Dr. Maibach's declaration, and this response, the Examiner erred in rejecting the pending claims. Applicant therefore respectfully asks the Examiner to withdraw the rejections and allow this application.

In the event that the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 425802000200. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: November 4, 2003

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